

REMARKS

Claims 1-33 are pending and are rejected. Claims 2, 3, and 25 are further amended. Applicant respectfully requests reconsideration for the following reasons, and appreciates the courtesy of a telephone interview with Examiner Kaushal, Primary Examiner Fredman, and applicant's undersigned representative on March 25, 2004.

Applicant has amended the dependent claims to further clarify that the claimed device contains distinct populations of dermal and epidermal cells. Although applicant asserts that the original claims clearly make this distinction, the relevant claims are amended to facilitate prosecution.

As part of this Amendment, applicant also submits the Declaration of Steven T. Boyce, Ph.D. describing how the Boyce, Med. Biol. Eng. & Comp. 36:791-800, 1998 publication does not anticipate the claimed invention. Dr. Boyce is both the inventor and author of cited publication.

The Declaration describes that Figure 1 in the publication does not disclose dermal cells on a biocompatible matrix to form a cellular lamination layer, as the claims require. This is because Figure 1 shows dermal cells uniformly filling the matrix, as confirmed by the figure legend which indicates "C-GAG-HF" as a single component (HF=human fibroblasts; C-GAG=collagen glycosaminoglycan).

Further, the Declaration states Dr. Boyce's opinion that the publication does not enable the claimed invention, and thus cannot anticipate it, even if Figure 1 was enabling which applicant respectfully but emphatically disputes. To constitute an anticipatory reference, the reference must contain an enabling disclosure. *In re Donohue*, 226 U.S.P.Q. 619 (Fed. Cir. 1985) (copy attached). The figure must be

evaluated for what it reasonably discloses and suggests to one of ordinary skill in the art, and show all the claimed structural features and how they are put together.

M.P.E.P. §§ 2121.04 and 2125.

The publication is not enabling at least because one of ordinary skill in this art could not taken its disclosure, with his or her own knowledge, to place himself or herself in possession of a cultured skin device, or a method of making a cultured skin device, with dermal cells on a matrix forming a lamination layer for epidermal cells.

There is no teaching, disclosure, or suggestion that this should be accomplished because the figure does not show this arrangement, as explained in the Declaration.

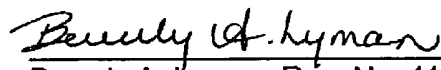
There is also no teaching, disclosure, or suggestion how to accomplish this, because no process steps are provided in the publication.

CONCLUSION

For the foregoing reasons, applicant's invention is believed to be patentable and an early Notice of Allowance is respectfully requested.

Applicant does not believe any fee is due with this submission. However, the Examiner is authorized to charge any fee deficiency to Deposit Account Number 23-3000. The Examiner is invited to telephone the undersigned attorney if there are any questions.

Respectfully submitted,
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